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13 UNITED STATES DISTRICT COURT  
14 CENTRAL DISTRICT OF CALIFORNIA  
15

16 ROSEANNE SANCHEZ, et al.,

17 Plaintiff,

18 v.  
19

20 BOSTON SCIENTIFIC CORPORATION,  
21

22 Defendants.  
23

Case No. CV 15-1245-JFW (JEMx)

**DEFENDANT'S OFFERS OF  
PROOF IN SUPPORT OF ITS  
AFFIRMATIVE DEFENSES**

**Pre-Trial Conference: April 17, 2015**

**Trial: May 5, 2015**  
24

25 Pursuant to the Court's In Chamber Order of April 13, 2015 (Doc. 207),  
26 Defendant Boston Scientific Corporation ("Boston Scientific") submits the following  
27 offers of proof in support of its affirmative defenses.  
28

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**I. FIRST AFFIRMATIVE DEFENSE: STATUTE OF LIMITATIONS**

California’s two-year statute of limitations bars Plaintiffs’ claims. CAL. CIV. PROC. CODE § 335.1. Plaintiffs filed this personal-injury action on September 21, 2012. However, the uncontroverted facts establish that Ms. Sanchez discovered her cause of action more than two years before filing suit. Ms. Sanchez was, at the least, on inquiry notice well outside the limitations period and failed to timely file.

Under California law, a cause of action accrues “when under the substantive law, the wrongful act is done, or the wrongful result occurs.” *Unruh-Haxton v. Regents of Univ. of Cal.*, 162 Cal. App. 4th 343, 358, 76 Cal. Rptr. 3d 146, 158-59 (Cal. Ct. App. 2008) (quoting *Norgart v. Upjohn Co.*, 21 Cal. 4th 383, 397, 981 P.2d 79, 88 (1999) (internal quotation marks omitted)). California recognizes the “discovery rule.” A plaintiff discovers a cause of action under California law when she suspects a “factual basis” for its elements. *Id.* at 397. Ms. Sanchez had a sufficient “factual basis” to conclude that “someone had done something wrong” when she had to undergo revision surgery outside the limitations period. See *Norgart*, 21 Cal. 4th at 397.

Ms. Sanchez underwent four surgical revision procedures to remove mesh, one of which was under anesthesia, prior to September 21, 2010, and therefore outside the two-year limitations period. Moreover, Ms. Sanchez’s implanting physician, Dr. Wiltchik, diagnosed her as having “complications due to genitourinary device, graft, and implant” six times outside the limitations period. Under California law, such undisputed facts are more than sufficient to put a plaintiff on notice of a potential cause of action. See, e.g., *Coleman v. Boston Scientific Corp.*, 1:10-CV-01968-OWW, 2011 WL 3813173, at \*3 (E.D. Cal. Aug. 29, 2011). Despite possessing these facts, Plaintiffs waited more than two years to file suit. Accordingly, all of Plaintiffs’ claims are barred.

The medical records and testimony are clear – Ms. Sanchez had actual knowledge of her cause of action outside the limitations period. However, to the

1 extent Ms. Sanchez denies actual knowledge of her cause of action, she was – at the  
2 very least – on inquiry notice more than two years before filing her case. Under  
3 California law, actual knowledge of the harm is not required for a claim to accrue.  
4 *Norgart*, 21 Cal. 4th at 398 n.3. Instead, the standard is whether plaintiff has “notice  
5 or information of circumstances to put a reasonable person on inquiry.” *Jolly v. Eli*  
6 *Lilly & Co.*, 44 Cal. 3d 1103, 1110-11, 751 P.2d at 927-28 (quoting *Gutierrez v.*  
7 *Mofid*, 39 Cal. 3d 892, 896 (1985)). The discovery rule is an objective standard. *Id.* It  
8 holds a plaintiff to both “her actual knowledge as well as knowledge that could  
9 reasonably be discovered through investigation of sources open to her.” *Id.* at 1109.  
10 Therefore, even if Ms. Sanchez claims she lacked knowledge, she must be held to  
11 what a reasonable inquiry by a reasonable person would have revealed. *See id.* at  
12 1109-11. A plaintiff must exercise reasonable diligence in pursuing claims and  
13 “[l]ack of knowledge alone is not sufficient to stay a statute; a plaintiff may not  
14 disregard reasonably available avenues of inquiry which, if vigorously pursued, might  
15 yield the desired information.” *Bernson v. Browning-Ferris Indus.*, 7 Cal. 4th 926,  
16 936 (1994).

17 Finally, there is no requirement that plaintiffs be aware of all the facts necessary  
18 for a legal claim. *See Jolly*, 44 Cal. 3d at 1111. For example, plaintiffs may argue that  
19 they must be aware of the specific “product defect” before a cause of action accrues.  
20 But as *Jolly* held: “a plaintiff need not be aware of the specific ‘facts’ necessary to  
21 establish the claim; that is a process contemplated by pretrial discovery.” *Id.*  
22 Regardless of Ms. Sanchez’s purported actual knowledge, she was on inquiry notice  
23 by no later than April 2010 due to her medical records and alleged complications. The  
24 available facts and information were more than sufficient for a reasonable person to  
25 have a suspicion of wrongdoing. And “[o]nce the plaintiff has a suspicion of  
26 wrongdoing, and therefore an incentive to sue, she must decide whether to file suit or  
27 sit on her rights.” *Id.*

1           **A. Elements Required to Establish Defendant's First Affirmative**  
2           **Defense: Statute of Limitations.**

3           The elements of this affirmative defense are:

- 4                     1. Boston Scientific must prove that Rosanne Sanchez's claimed  
5 harm occurred before September 21, 2010.
- 6                     2. If Boston Scientific proves that Rosanne Sanchez's claimed harm  
7 occurred before September 21, 2010, Rosanne Sanchez's lawsuit was still filed on  
8 time if Rosanne Sanchez proves that before that date, Rosanne Sanchez did not  
9 discover, and did not know of facts that would have caused a reasonable person to  
10 suspect, that she had suffered harm that was caused by someone's wrongful conduct.  
11 See CACI 454, 455.

12

13           The following witnesses will offer testimony in support of this affirmative  
14 defense:

15           **B. Offer of Proof for Witness Rosanne Sanchez:**

16           Ms. Sanchez will testify that starting immediately after her surgery of January  
17 13, 2010 she began to have abnormal vaginal discharge, pelvic discomfort, and pain.  
18 See Rosanne Sanchez Deposition ("Ms. Sanchez Dep.") 235:6-12, **Exhibit 1**. She will  
19 also testify that she has noticed spotting and discharge "every day" since her initial  
20 surgery. *Id.* at 20:22-21:14, Ex. 1. Ms. Sanchez will testify that she continually wore  
21 pads and panty liners between her initial surgery on January 13, 2010, and April 9,  
22 2010. Ms. Sanchez Dep. at 219:14-21, Ex. 1.

23           Ms. Sanchez will be shown statements from the medical records maintained by  
24 Dr. Wiltchik's practice regarding her care and treatment. These records will establish  
25 that on January 26, 2010, Ms. Sanchez complained to Dr. Wiltchik of "vaginal  
26 discharge thin and watery, associated with itching." Medical Records of Dr. Wiltchik  
27 ("Wiltchik Records") 52. She will be shown statements in her records establishing that

1 on February 15, 2010 she complained to Dr. Wiltchik of “tan colored and foul  
2 smelling” vaginal discharge and abdominal cramping. *Id.* at 50.

3 Ms. Sanchez will testify consistent with her Plaintiff’s Fact Sheet that she  
4 claims she has suffered from “recurring odorous discharge, occasional bleeding,  
5 infections, recurrence of exposed mesh, painful sexual intercourse, recurrence of  
6 incontinence and abdominal and vaginal pain” and that she first saw a health-care  
7 provider for each of these alleged bodily injuries in February 2010. *See* Plaintiff’s Fact  
8 Sheet, p. 6; *see also*, Ms. Sanchez Dep. 13:25-15:25; 18:20-19:18; 20:20-21:14;  
9 22:14-23:2; 217:24-219:4; 232:16-233:3, Ex. 1.

10 Ms. Sanchez will testify that on April 9, 2010 she complained to Dr. Wiltchik  
11 of “abnormal vag[inal] bleeding scant with a pink discharge which cause[d] her to  
12 wear a daily panty liner,” and described feeling “something scratchy like a stitch in  
13 her vagina.” Wiltchik Records at 46; Ms. Sanchez Dep. at 219:5-220:6, Ex. 1; *see*  
14 *also*, Deposition of Dr. Wiltchik (“Wiltchik Dep.”) 47:18-23; 184:3-14, **Exhibit 2**.  
15 She will also testify consistent with her records that Dr. Wiltchik assessed her at that  
16 time as having “complications due to genitourinary device, graft, and implant.” *Id.*; *see*  
17 *also*, Wiltchik Dep. 49:8-23, Ex. 2. She will also testify consistent with her records  
18 that on that same day, Dr. Wiltchik completed an in-office procedure wherein a “small  
19 amount of exposed mesh...was excised and silver nitrate applied.” *Id.*; *see also*,  
20 Wiltchik Dep. 49:3-7; 49:24-50:3, Ex. 2. Ms. Sanchez will testify that she understood  
21 that this procedure was required because “the skin was not healing over the mesh.”  
22 Ms. Sanchez Dep. 220:20:-221:21, Ex. 1. She will testify that she recalls Dr. Wiltchik  
23 drawing a picture for her describing where the mesh was “sticking out.” *Id.* She will  
24 also testify consistent with her records that she understood “that a few treatments  
25 [would] be required before the exposed mesh areas [were] completely covered and her  
26 symptoms [would] resolve.” Wiltchik Records 46. She will further testify that at that  
27

1 time, Dr. Wiltchik prescribed Vagifem to help with the healing process. Ms. Sanchez  
2 Dep. at 221:22-222:4, Ex. 1.

3 Ms. Sanchez will testify consistent with her medical records that on May 3,  
4 2010, for the second time, Dr. Wiltchik assessed Ms. Sanchez as having  
5 “complications due to genitourinary device, graft, and implant.” Wiltchik Records 44;  
6 *see also*, Wiltchik Dep. 49:8-23, Ex. 2. She will also testify consistent with her  
7 records that on that day, Dr. Wiltchik again excised a “small amount of exposed  
8 mesh.” Wiltchik Records 44; *see also*, Wiltchik Dep. 49:24-50:3, Ex. 2.

9 Ms. Sanchez will testify that on May 20, 2010, she was experiencing pain  
10 associated with a vaginal infection, including pelvic cramping and discomfort, and her  
11 incontinence symptoms had returned. Ms. Sanchez Dep. 225:6-16; 225:24-226:2, Ex.  
12 1. She will testify that Dr. Wiltchik prescribed her MetroGel-Vaginal gel to treat these  
13 complications. Wiltchik Records 43; Ms. Sanchez Dep. 224:4-17, Ex. 1.

14 Ms. Sanchez will testify consistent with her medical records that on June 14,  
15 2010, she complained to Dr. Wiltchik of pink tinged vaginal discharge increasing in  
16 amount that was “thought to be due to her exposed mesh.” Wiltchik Records 41. She  
17 will be shown medical records establishing that she had been using Vagifem without  
18 improvement, was “very frustrated,” and desired “definitive treatment.” *Id.* She will  
19 also be shown records establishing that Dr. Wiltchik again assessed her as having  
20 “complications due to genitourinary device, graft, and implant.” *Id.* at 42. She will be  
21 shown records establishing that after a “lengthy discussion” with Dr. Wiltchik, Ms.  
22 Sanchez “decided to proceed with an excision of exposed mesh under anesthesia.  
23 Risks, benefits, and alternatives were discussed with the patient and informed consent  
24 was obtained and signed.” *Id.* She will testify that she understood that during the  
25 procedure, “it [was] possible that they would be able to do something that would stop  
26 the mesh from wanting to come out of the vaginal wall.” Ms. Sanchez Dep. at 230:3-  
27 6, Ex. 1. She will also testify that she understood that at the time of this procedure,

1 excising the mesh could result in the return of her incontinence symptoms. *Id.* at  
2 230:7-13, Ex. 1. She will testify that she remembers this discussion with Dr. Wiltchik  
3 and signed the consent form, which specifically indicated the procedure was intended  
4 for “excision of exposed mesh.” *See* Ms. Sanchez Dep. 229:15-230:13; 230:16-  
5 231:23, Ex. 1; Santa Maria Medical Records (“Santa Maria Records”) 7-9.

6 Ms. Sanchez will be shown records establishing that on June 18, 2010, Dr.  
7 Wiltchik performed the third excision of exposed mesh from Ms. Sanchez. Wiltchik  
8 Records 80; Santa Maria Records 7-9; Wiltchik Dep. 51:2-19, Ex. 2.

9 Ms. Sanchez will testify consistent with her medical records that on July 2,  
10 2010 she complained to Dr. Wiltchik of “vaginal discharge occasionally blood tinged  
11 without any odor or irritation.” Wiltchik Records at 39.

12 Ms. Sanchez will testify consistent with her medical records that on September  
13 1, 2010, Ms. Sanchez complained to Dr. Wiltchik of “abnormal vag[inal] bleeding  
14 small amount of pink tinged discharge,” and “discomfort with intercourse.” *Id.* at 35;  
15 Ms. Sanchez Dep. 233:4-19, Ex. 1. Ms. Sanchez will testify that at that time “it fe[lt]  
16 as if her husband [could not] fully penetrate due to her pain.” Wiltchik Records 35;  
17 Ms. Sanchez Dep. 233:4-23, Ex. 1. She will testify consistent with her medical  
18 records that Dr. Wiltchik assessed her as having “complications due to genitourinary  
19 device, graft, and implant.” *Id.* Ms. Sanchez will be shown records establishing that  
20 on that same day, Dr. Wiltchik excised a portion of the mesh from Ms. Sanchez and  
21 applied silver nitrate. Wiltchik Records at 35; Ms. Sanchez Dep. 234:11-25, Ex. 1.  
22 The records establish that, “[p]atient understands her symptoms are due to a small  
23 amount of exposed mesh.” *Id.* Ms. Sanchez will testify that at the time of this  
24 appointment, she had been experiencing “on and off” general pelvic pain and she was  
25 still experiencing general pain, pain with intercourse, and discharge. Ms. Sanchez  
26 Dep. 234:7-10, 235:6-12, Ex. 1. She will also testify that she was experiencing  
27 symptoms of stress urinary incontinence. *Id.* at 235:12-17, Ex. 1. Ms. Sanchez will  
28

1 also testify that by this date, her husband Rod Sanchez had experienced abrasions on  
2 his penis as a result of the mesh. *Id. See also, id.* at 116:8-119:10, Ex. 1; Rod Sanchez  
3 Deposition (“Mr. Sanchez Dep.”) at 52:13-53:17, **Exhibit 3**.

4 Ms. Sanchez will testify consistent with her medical records that on September  
5 17, 2010 she saw Dr. Wiltchik for spotting and discharge. Wiltchik Records 33. She  
6 will be shown statements in her records establishing that upon examination, Dr.  
7 Wiltchik discovered a “large area of mesh exposed in the midline and mucosa  
8 bleeding.” *Id.* Ms. Sanchez will also be shown statements in her medical records  
9 establishing that, for the sixth time, Dr. Wiltchik assessed Ms. Sanchez as having  
10 “complications due to genitourinary device, graft, and implant.” *Id.* She will testify  
11 consistent with her records that, after a “lengthy discussion,” she decided to proceed  
12 with an “excision of exposed mesh and perineorrhaphy” under general anesthesia. *Id.*

13 Ms. Sanchez’s Short Form Complaint will show that she filed her lawsuit on  
14 September 21, 2012. *See* Short Form Complaint.

15 All of the above testimony, Plaintiff’s medical records, and other documents  
16 will show that Ms. Sanchez’s claimed harm occurred before September 21, 2010,  
17 and/or that she discovered the facts that would have caused a reasonable person to  
18 suspect that she had suffered harm. This testimony will also show that Ms. Sanchez  
19 was, at the very least, on inquiry notice of her claims.

20 Ms. Sanchez will also testify that as a nurse she had pre-existing knowledge  
21 about uterine and vaginal prolapse, stress urinary incontinence, and professional  
22 experience learning about and even helping patients with risks and side effects of  
23 medical treatment. *See* Ms. Sanchez Dep. 94:25-95:9; 98:25-100:3, 97:10-98:12;  
24 103:16-105:21, Ex. 1. Moreover, Ms. Sanchez will testify that, prior to her Pinnacle  
25 implant procedure, Dr. Wiltchik informed her of the risks associated with the  
26 procedure. Ms. Sanchez Dep. 190:13-192:6, Ex. 1; *see also*, Wiltchik Dep. at 145:19-  
27 146:20; 146:24-147:5; 147:15-148:15; 148:16-149:12, Ex. 2. Ms. Sanchez will also

be shown statements from the medical records that indicate she signed an informed consent prior to her mesh procedure. Marian Regional Medical 115-118; Wiltchik Records 54-55. This testimony will show that Ms. Sanchez was, at the very least, on inquiry notice of her claims.

**1. Documents To Be Used With The Witness:**

	<b>Title</b>	<b>Author</b>	<b>Date</b>	<b>Ex. Number</b>
1.	Rosanne Sanchez's Plaintiff's Fact Sheet	Rosanne Sanchez	Undated	Def. Ex. 10
2.	Short Form Complaint	Rosanne and Rod Sanchez	09/21/10	Def. Ex. 23
3.	Rosanne Sanchez's Deposition	[n/a]	07/18/13	[n/a—Will not be offered into evidence; will be used only for impeachment purposes]
4.	Rod Sanchez's Deposition	[n/a]	07/19/13	[n/a—Will not be offered into evidence; will be used only for impeachment purposes]
5.	Dr. Kerri Wiltchik Deposition	[n/a]	07/11/13	[n/a—Will not be offered into evidence; will be used only for impeachment purposes]
6.	Santa Maria Medical Records	Healthcare Professionals	Various	Joint Ex. 15
7.	Marian Regional	Healthcare	Various	Joint Ex. 15

1		Medical Records	Professionals		
2	8.	Dr. Wiltchik	Healthcare	Various	Joint Ex. 15
3		Medical Records	Professionals		
4					

**C. Offer of Proof for Witness Dr. Kerry Wiltchik, M.D.:**

Dr. Wiltchik will testify, consistent with the medical records maintained by her practice, that on January 26, 2010 Ms. Sanchez complained to Dr. Wiltchik of “vaginal discharge thin and watery, associated with itching.” Wiltchik Records 52. She will also testify consistent with the records that on February 15, 2010, Ms. Sanchez complained to Dr. Wiltchik of “tan colored and foul smelling” vaginal discharge and abdominal cramping. *Id.* at 50.

Dr. Wiltchik will testify that on April 9, 2010, Ms. Sanchez complained to Dr. Wiltchik of “abnormal vag[inal] bleeding scant with a pink discharge which cause[d] her to wear a daily panty liner,” and described feeling “something scratchy like a stitch in her vagina.” Wiltchik Dep. 47:18-23; 184:3-14, Ex. 2; Wiltchik Records 46. She will testify that Ms. Sanchez was “frustrated and desire[d] definitive treatment.” Wiltchik Dep. at 47:24-48:3, Ex. 2. She will testify that on April 9, 2010, she assessed Ms. Sanchez as having “complications due to genitourinary device, graft, and implant.” Wiltchik Records 46; Wiltchik Dep. 49:8-23, Ex. 2. Dr. Wiltchik will also testify that on April 9, 2010, she completed an in-office procedure on Ms. Sanchez wherein a “small amount of exposed mesh . . . was excised and silver nitrate applied.” *Id.* at 49:3-7; 49:24-50:3, Ex. 2. Wiltchik Records 46. Dr. Wiltchik will testify that Ms. Sanchez understood “that a few treatments [would] be required before the exposed mesh areas [were] completely covered and her symptoms [would] resolve.” Wiltchik Records 46; Wiltchik Dep. 185:4-186:3. Ex. 2.

1 Dr. Wiltchik will testify that on May 3, 2010, for the second time, she assessed  
2 Ms. Sanchez as having “complications due to genitourinary device, graft, and  
3 implant.” Wiltchik Records 44; Wiltchik Dep. 49:8-23, Ex. 2. She will testify that she  
4 once again excised a “small amount of exposed mesh” from Ms. Sanchez. Wiltchik  
5 Records 44; Wiltchik Dep. 49:24-50:3, Ex. 2.

6 Dr. Wiltchik will testify consistent with the records that on May 20, 2010, for  
7 the third time, she assessed Ms. Sanchez as having “complications due to  
8 genitourinary device, graft, and implant,” and also bacterial vaginosis. Wiltchik  
9 Records 43.

10 Dr. Wiltchik will testify consistent with the records that on June 14, 2010, Ms.  
11 Sanchez complained to Dr. Wiltchik of pink tinged vaginal discharge increasing in  
12 amount that was “thought to be due to her exposed mesh.” Wiltchik Records 41. Dr.  
13 Wiltchik will testify consistent with the records that Ms. Sanchez had been using  
14 Vagifem without improvement, was “frustrated,” and desired “definitive treatment.”  
15 *Id.* Dr. Wiltchik once again assessed Ms. Sanchez as having “complications due to  
16 genitourinary device, graft, and implant.” *Id.* at 42. Dr. Wiltchik will testify  
17 consistent with the records that after a “lengthy discussion” with her, Ms. Sanchez  
18 “decided to proceed with an excision of exposed mesh under anesthesia. Risks,  
19 benefits, and alternatives were discussed with the patient and informed consent was  
20 obtained and signed.” *Id.* Dr. Wiltchik will testify that on June 18, 2010, after Ms.  
21 Sanchez executed a consent form, she performed the third excision of exposed mesh  
22 from Ms. Sanchez and applied silver nitrate. Wiltchik Dep. 51:2-19, Ex. 2; Santa  
23 Maria Records 7-9; Wiltchik Records 80-81.

24 Dr. Wiltchik will testify consistent with the records that on July 2, 2010, Ms.  
25 Sanchez complained to her of “vaginal discharge occasionally blood tinged without  
26 any odor or irritation.” Wiltchik Records 39.

1 Dr. Wiltchik will testify consistent with the records that on September 1, 2010,  
2 Ms. Sanchez complained to Dr. Wiltchik of “abnormal vag[inal] bleeding small  
3 amount of pink tinged discharge,” and “discomfort with intercourse” and that “it fe[lt]  
4 as if her husband [could not] fully penetrate due to her pain.” *Id.* at 35. Dr. Wiltchik  
5 will testify consistent with the records that she assessed Ms. Sanchez as having  
6 “complications due to genitourinary device, graft, and implant.” *Id.* Dr. Wiltchik will  
7 testify consistent with the records that she also excised a portion of mesh from Ms.  
8 Sanchez and applied silver nitrate at that visit. *Id.* The records state that on September  
9 1, 2010, Ms. Sanchez “understands her symptoms are due to a small amount of  
10 exposed mesh.” *Id.*

11 Dr. Wiltchik will testify consistent with the records that on September 17, 2010,  
12 Ms. Sanchez saw her for spotting and discharge. *Id.* at 33. Upon examination, Dr.  
13 Wiltchik discovered a “large area of mesh exposed in the midline and mucosa  
14 bleeding.” *Id.* Dr. Wiltchik will testify consistent with the records that, for the sixth  
15 time, she assessed Ms. Sanchez as having “complications due to genitourinary device,  
16 graft, and implant.” *Id.* Dr. Wiltchik will testify consistent with the records that after  
17 a “lengthy discussion,” Ms. Sanchez decided to proceed with an “excision of exposed  
18 mesh and perineorrhaphy” under general anesthesia. *Id.*

19 All of the above testimony, medical records, and other documents will show  
20 that Ms. Sanchez’s claimed harm occurred before September 21, 2010 and/or that she  
21 discovered the facts that would have caused a reasonable person to suspect that she  
22 had suffered harm. This testimony will also show that Ms. Sanchez was, at the very  
23 least, on inquiry notice of her claims.

24 Dr. Wiltchik will also testify that she was aware of the 2008 FDA PHN and the  
25 risks it articulated at the time it came out. Wiltchik Dep. 27:19-28:15; 153:3-154:5;  
26 154:10-155:18, Ex. 2. The 2008 PHN will establish that there were ample sources of  
27 publicly available information available to Dr. Wiltchik and Ms. Sanchez regarding  
28

the potential complications of the Pinnacle. *See* 2008 FDA PHN, available at [www.fda.gov/medicaldevices/safety/alertsandnotices/publichealthnotifications/ucm061976.htm](http://www.fda.gov/medicaldevices/safety/alertsandnotices/publichealthnotifications/ucm061976.htm) (last visited April 15, 2015). Dr. Wiltchik will also testify that she understood there were risks associated with the use of POP mesh devices such as the Pinnacle as early as 2004. Wiltchik Dep. at 126:23-127:17, Ex. 2. Dr. Wiltchik will also testify that she reviewed the Pinnacle DFU at some point in the past and was aware at the time of placing Ms. Sanchez' Pinnacle of the potential complications listed in the DFU. *Id.* at 137:8-16; 138:2-11; 145:19-146:20; 148:16-149:6; 150:8-152:12; 154:10-155:18, Ex. 2; *see also*, Pinnacle Pelvic Floor Repair Kit Directions for Use ("Pinnacle DFU"). Moreover, she communicated these potential complications to Ms. Sanchez. Wiltchik Dep. at 145:19-146:20; 146:24-147:5; 147:15-148:15; 148:16-149:12, Ex. 2. This testimony will show that Ms. Sanchez was, at the very least, on inquiry notice of her claims because she and Dr. Wiltchik were aware of the potential risks of pelvic mesh including those complications allegedly suffered by Ms. Sanchez.

**1. Documents To Be Used With The Witness:**

	<b>Title</b>	<b>Author</b>	<b>Date</b>	<b>Ex. Number</b>
1.	Rosanne Sanchez's Deposition	[n/a]	07/18/13	[n/a—Will not be offered into evidence; will be used only for impeachment purposes]
2.	Dr. Kerri Wiltchik Deposition	[n/a]	07/11/13	[n/a—Will not be offered into evidence; will be used only for impeachment purposes]
3.	Santa Maria	Healthcare	Various	Def. Ex. 15

	Medical Records	Professionals		
4.	Marian Regional Medical Records	Healthcare Professionals	Various	Def. Ex. 15
5.	Dr. Wiltchik Medical Records	Healthcare Professionals	Various	Def. Ex.15
6.	FDA Public Health Notification: Serious Complications Associated with Transvaginal Placement of Surgical Mesh in Repair of POP and SUI	Healthcare Professionals	October 20, 2008	[n/a—Publicly available document for which Court may take judicial notice, available at <a href="http://www.fda.gov/medicaldevices/safety/alertsandnotices/publichealthnotifications/ucm061976.htm">www.fda.gov/medicaldevices/safety/alertsandnotices/publichealthnotifications/ucm061976.htm</a> .]
7.	Pinnacle Pelvic Floor Repair Kits Anterior/Apical Directions for Use	Boston Scientific Corp.	12/12/07	Def. Ex. 6

**D. Offer of Proof for Witness Dr. Matthew Davies, M.D.:**

Dr. Davies will offer testimony on Ms. Sanchez's post-implant medical course, including her four surgical revision procedures to remove mesh, which occurred prior

1 to September 21, 2010. Dr. Davies will testify live at trial and has offered information  
2 and opinions in his expert report.

3 Dr. Davies will testify that on January 26, 2010, Ms. Sanchez was at a 2 week  
4 post-operative checkup and her pelvic exam showed the vagina was healing well, but  
5 bacterial vaginosis was diagnosed and oral clindamycin was used to treat it.

6 Dr. Davies will testify that on February 15, 2010, Ms. Sanchez was 5 weeks  
7 post-operative, complaining of a vaginal discharge that is tan- colored and foul  
8 smelling. She was treated this time with Flagyl.

9 Dr. Davies will testify that on April 9, 2010, Ms. Sanchez was three months  
10 status post-surgery and she had vaginal bleeding with a pink discharge necessitating  
11 the use of a panty liner daily. She was also feeling a scratchy sensation inside the  
12 vagina and requests definitive treatment. She had no pelvic pain, no dyspareunia, and  
13 no dysuria. On examination, there was a small amount of exposed mesh on the cuff at  
14 the nine o'clock position, which was excised and treated with silver nitrate. There was  
15 also midline concern of the pending mesh erosion. She was started on estrogen vaginal  
16 replacement.

17 Dr. Davies will testify that on May 3, 2010, Ms. Sanchez was four months  
18 status post-surgery. On exam, there was again a small amount of exposed mesh at the  
19 nine o'clock, which is exactly the same position as it was at the last visit. It again was  
20 excised and silver nitrate was reapplied. Again the midline of the anterior mucosa was  
21 thin, which is concerning for a pending mesh erosion, but none is noted that day. She  
22 was to continue with the Vagifem intravaginally.

23 Dr. Davies will testify that on May 20, 2010, Ms. Sanchez was diagnosed with  
24 bacterial vaginosis and she was treated with metro gel, intravaginally.

25 Dr. Davies will testify that on June 14, 2010, Ms. Sanchez was five months  
26 status post-surgery. She reported a decent amount of vaginal discharge that is pink  
27 tinged. She had been using the Vagifem without improvement. On exam, there was a  
28

1 large amount of exposed mesh in the midline and large amounts of pink tinged  
2 discharge.

3 Dr. Davies will testify that on June 18, 2010, Ms. Sanchez underwent excision  
4 of exposed mesh in the operating room and a 5mm portion of mesh was excised while  
5 the vagina epithelium was undermined and then approximated.

6 Dr. Davies will testify that on July 2, 2010, Ms. Sanchez was two weeks status  
7 post-operative excision of mesh exposure. She had some vaginal discharge that was  
8 bloody but she had no pain with urination.

9 Dr. Davies will testify that on September 1, 2010, Ms. Sanchez presented  
10 approximately two and a half months out from her vaginal mesh exposure excision.  
11 She complained of abnormal vaginal bleeding and a small amount of pink discharge.  
12 She also had discomfort with intercourse and she stated that her husband could not  
13 fully penetrate her due to her pain. She had no dysuria and no other pelvic pain. On  
14 exam there was a midline defect noted of exposed mesh. The mesh was excised in the  
15 office and silver nitrate is applied.

16 Dr. Davies will testify that on September 17, 2010, Ms. Sanchez has some  
17 spotting and discharge. On her gynecological exam, a large area of mesh is exposed in  
18 the midline and is bleeding. She was scheduled for a repeat attempt at excision and  
19 closure in the operating room. Again, the exposure area in the midline was appreciated  
20 and the mucosa is bleeding. The patient was scheduled for the mesh excision. A  
21 perineorrhaphy was also scheduled for the same time.

22 All of the above testimony, medical records, and other documents will show  
23 that Ms. Sanchez's claimed harm occurred before September 21, 2010 and/or that she  
24 discovered the facts that would have caused a reasonable person to suspect that she  
25 had suffered harm. This testimony will also show that Ms. Sanchez was, at the very  
26 least, on inquiry notice of her claims.

Dr. Davies will also testify, consistent with the information offered in his expert report, that at the time of Ms. Sanchez's implant, physicians were aware of the potential complications associated with the prolapse surgeries, including the Pinnacle procedure. Dr. Wiltchik testified that she was aware of these potential risks. Moreover, the complications associated with the Pinnacle were articulated in the DFU. *See* Pinnacle DFU. This testimony will show that Ms. Sanchez was, at the very least, on inquiry notice of her claims because her physician, Dr. Wiltchik, was aware of the potential risks of pelvic mesh including those complications allegedly suffered by Ms. Sanchez.

**1. Documents To Be Used With The Witness:**

	<b>Title</b>	<b>Author</b>	<b>Date</b>	<b>Ex. Number</b>
1.	Santa Maria Medical Records	Healthcare Professionals	Various	Joint Ex. 15
2.	Marian Regional Medical Records	Healthcare Professionals	Various	Joint Ex. 15
3.	Dr. Wiltchik Medical Records	Healthcare Professionals	Various	Joint Ex.15
4.	Pinnacle Pelvic Floor Repair Kits Anterior/Apical Directions for Use	Boston Scientific Corp.	12/12/07	Def. Ex. 6

**II. SECOND AFFIRMATIVE DEFENSE: COMPARATIVE FAULT OF  
THIRD PERSON**

Based on plaintiffs' key evidence set forth in the Pre-Trial Conference Order and in plaintiffs' deposition designations, it appears plaintiffs intend to assert and offer evidence in support of their causes of action that Boston Scientific had a feasible alternative design and/or knew of a safer alternative and that Boston Scientific "had actual or constructive knowledge that the larger the size of a permanent mesh implant, the more likely the potential would be for post-implant erosion," and that Dr. Roger Goldberg had "actual or constructive knowledge...that the mesh configuration for the Pinnacle PFR Kit was too large and would likely cause erosions and extrusions." (Final Pre-Trial Conference Order (Dkt. No. 194) at 15:8–15, 17:24–18:4, 24:10–17.)

If plaintiffs pursue these arguments and offer such evidence, then they are opening the door to the contention that Dr. Wiltchik was negligent in her selection of the Pinnacle. Boston Scientific's Uphold was on the market at the time Dr. Wiltchik selected the Pinnacle for treatment of Mrs. Sanchez's pelvic organ prolapse. While Boston Scientific disputes that the Uphold is a safer alternative design for the Pinnacle, and opposes the introduction of evidence regarding other products not at issue in this action, including the Uphold, if the Court allows plaintiffs to argue that the Uphold was a safer alternative design and it was negligent to implant the Pinnacle when the Uphold was available, the jury should be allowed to apportion fault to Dr. Wiltchik, who had sole discretion to choose the product for implantation in Ms. Sanchez.

In addition, there are issues with Dr. Wiltchik's treatment of Mrs. Sanchez that enable a jury to apportion liability, if any, between Boston Scientific and Dr. Wiltchik. First, there is an indication that the Pinnacle mesh was located in the wrong surgical plane, including that hydrodissection was not properly done. *See* Marian Records 125-127 (describing placement of the mesh by "tunneling" under the mucosa); Dr.

1 Kerri Wiltchik Medical Records (“Wiltchik Records”) at 21–22 (describing treatment  
2 of erosion by LEEP procedure). Second, Ms. Sanchez has undergone not one, but  
3 two, perineorrhaphies or levator myorrhaphies. A levator myorrhaphy is a type of  
4 posterior repair involving plication of the levator ani muscles. In this type of repair, it  
5 is not the connective tissue on top of the rectum that is plicated from side-to-side, but  
6 rather, the muscular tissue of the side wall that a surgeon stitches on either side to  
7 meet in the midline. *See* Marian Records at 125–127. These operative choices and  
8 techniques of Dr. Wiltchik may be a substantial factor in causing plaintiffs’ alleged  
9 dyspareunia and/or the mesh erosion alleged by Ms. Sanchez.<sup>1</sup>

10  
11 **A. Elements Required to Establish Defendant’s Second Affirmative**  
12 **Defense: Comparative Fault of Third Person.**

- 13 1. That Dr. Wiltchik was negligent; and  
14 2. That this negligence was a substantial factor in causing Rosanne  
15 Sanchez’s harm.

16 *See* CACI 432.

17 The following witnesses will offer testimony in support of this affirmative  
18 defense:

19 **B. Offer of Proof for Witness Dr. Carol Karamitsos:**

20 Dr. Karamitsos assisted Dr. Wiltchik for Ms. Sanchez’s surgical procedure.  
21 Karamitsos Dep. at 32:17–19, Ex. 4. Dr. Karamitsos will provide testimony regarding  
22 the procedures performed on Ms. Sanchez. *Id.* at 46:20–47:1, 50:21–52:9, 52:18–22,  
23 53:2–9, 53:16–54:12, 58:20–59:25.

24  
25  
26 <sup>1</sup> Even if the Court concludes that Dr. Wiltchik was not negligent and fault should not  
27 be apportioned, Boston Scientific is separately entitled to introduce evidence and  
28 argue that various other circumstances and factors, including techniques utilized and  
other procedures selected by the treating physicians, caused or contributed to Ms.  
Sanchez’s claimed injuries.

1 Dr. Karamitsos will also testify that she has criticism of Dr. Wiltchik because of  
2 the differing techniques she used. Karamitsos Dep. at 85:13-16, 86:19-87:5. Dr.  
3 Karamitsos will testify that Dr. Wilchik did not perform a hydrodissection during the  
4 implant procedure. Karamitsos Dep. at 54:21-24. Dr. Wilchik instead used a  
5 sharpened blunt dissection. *Id.* at 55:23-54:3. It is Dr. Karamitsos' custom and  
6 practice to perform a hydrodissection. *Id.* at 55:5-9. A hydrodissection generally  
7 injects saline into the plane of tissue that the implanter intends to place the mesh. *Id.*  
8 at 55:21-22.

9 Dr. Karamitsos will testify that she employs more hydrodissection than Dr.  
10 Wiltchik performed on Ms. Sanchez during the implant procedure. Karamitsos Dep.  
11 at 87:20-88:10. Dr. Karamitsos will testify that she would typically infiltrate up to 60  
12 cc's of injectable saline into the anterior and posterior spaces, which is more fluid than  
13 Dr. Wiltchik used in Ms. Sanchez's procedure. *Id.* at 88:12-89:6. The medical  
14 records will show that Dr. Wiltchik only used 10 cc's of lidocaine, which Dr.  
15 Karamitsos will testify is not sufficient. *Id.* at 105:4-106:18, 107:13-21. As she will  
16 describe, Dr. Karamitsos' method opens up the space, allowing her to see if it  
17 blanches; thereby visualizing whether the opening was too superficial. Using  
18 hydrodissection, if she could see more of a rise overall, it would be indicative of a  
19 space that is deeper and more appropriate for mesh placement. *Id.* at 88:14-20. Dr.  
20 Karamitsos will testify that using less volume for hydrodissection could lead to  
21 superficial placement of the device (*Id.* at 108:10-15), and that if she witnessed Dr.  
22 Wiltchik not performing a hydrodissection for Ms. Sanchez's procedure today, she  
23 would tell her that she thinks Dr. Wiltchik should use hydrodissection to dissect. *Id.*  
24 at 97:20-23.

25 Further, Dr. Karamitsos will testify that she does not tack the mesh down in the  
26 midline, she would secure it laterally and try to avoid more of a medial placement of  
27 the suture material. *Id.* at 89:10-13. Dr. Karamitsos would also do the sling and then  
28

1 finish with the perineorrhaphy, while Dr. Wiltchik performed the perineorrhaphy and  
2 then did the sling. *Id.* at 90:4–6. Dr. Karamitsos will testify that the method she  
3 employs provides for better exposure with a vaginal hiatus that was more capacious  
4 than narrowed down already. *Id.* at 90:6–9; *see also id.* at 91:3–10.

5 Dr. Karamitsos will also testify that she uses different techniques when dealing  
6 with mesh extrusion. Karamitsos Dep. at 85:13–16, 93:2–95:2. Dr. Karamitsos has  
7 no idea whether other surgeons use Dr. Wiltchik’s technique. *Id.* at 83:17–19. Dr.  
8 Karamitsos will testify that when she treats mesh extrusion, she tries to hydrodissect  
9 around the area, just very minimally, to try to separate the plane. *Id.* at 93:10–94:2.  
10 This allows less tension on the extrusion so that she can excise the mesh that is  
11 exposed, and then she does not resect any of that mucosa. *Id.* at 94:3–9. She will  
12 testify that the procedure she uses helps to avoid tension on the tissue, and that  
13 avoiding tension is really important to help allow the area to heal appropriately, which  
14 once it is healed, there is no more mesh extrusion. *Id.* at 94:10–24. Dr. Karamitsos  
15 also does not recall ever performing a perineorrhaphy in connection with excision of  
16 mesh. *Id.* at 94:25–95:2. Dr. Karamitsos will testify that she also does not recall ever  
17 using silver nitrate in procedures to address mesh extrusion. *Id.* at 74:15–24.

18  
19 **1. Exhibits To Be Used With The Witness:**

	Title	Author	Date	Ex. Number
20				
21	1. Dr. Kerri Wiltchik	[n/a]	07/11/13	[n/a—Will not be offered into
22	Deposition			evidence; will be used only for
23				impeachment purposes]
24	2. Marian Regional	Healthcare	Various	Joint Ex. 15
25	Medical Records	Professionals		
26	[Bates Range 125-			
27	127]			

3.	Dr. Wiltchik Medical Records	Healthcare Professionals	Various	Joint Ex. 15
4.	Pinnacle Pelvic Floor Repair Kits Anterior/Apical Directions for Use	Boston Scientific Corp.	12/12/07	Def. Ex. 121

**C. Offer of Proof for Witness Dr. Matthew Davies:**

With regard to this affirmative defense, Dr. Davies will testify regarding the nature and manner of the procedures performed and associated details from Ms. Sanchez's implantation surgery in January 2010. More specifically, he will testify that, according to the operative note, Mrs. Sanchez underwent the vaginal hysterectomy, and the peritoneum, but not the cuff, was closed. He will testify that Dr. Wiltchik then moved on to the cystocele repair using some hydrodissection with 10 cc of lidocaine, and a vertical incision was made with the scalpel. A blunt dissection was used to tunnel out to the sacrospinous ligaments and the ischial spines. Sutures were placed on both sides to help anchor the mesh in its position. He will testify based on the operative note that the mesh arms were placed into the sacrospinous ligaments, and that while the note describes the lateral arms being placed, it does not specifically mention them going in to the arcus tendineus. He will testify that proximal sutures were threaded through to keep the mesh in place proximally and that excess mesh was trimmed and was tacked down with a single stitch in the midline distally near the urethra.

Dr. Davies will testify that with both of these incisions then open (the vaginal cuff and the anterior repair incision), the rectocele was then addressed. He will testify that the perineorrhaphy was dissected out and then a tunnel was made under the vaginal

1 mucosa going up to the posterior aspect of the vaginal cuff. He will further testify that  
2 a piece of mesh previously trimmed for the original anterior apical was then placed  
3 over the rectocele all the way up to the vaginal cuff. The sides were anchored in place  
4 with a single stitch of 2-0 vicryl and all the defects began to be closed. He will testify  
5 based on the medical records that the anterior vaginal mucosa was re-approximated  
6 with a single stitch of 0-vicryl and figure of eight sutures for hemostasis. Then the  
7 levator ani muscles were brought together in the midline, similar to a levator  
8 myorrhaphy. The posterior vaginal mucosa was trimmed and re-approximated with 0-  
9 vicryl in a running, locking stitch. Marian Records at 125–127.

10 Further, Dr. Davies will testify about how Dr. Wiltchik's technique increased  
11 the risk of erosion and poor healing because the mesh was located in the wrong  
12 surgical plane. He will explain how that if mesh is located in a superficial plane, the  
13 patient is at higher risk for erosion, and that Mrs. Sanchez' surgical mesh was located  
14 in the wrong surgical plane. Dr. Davies will confirm through the medical records that  
15 Mrs. Sanchez had a LEEP procedure done on April 25, 2011. Wiltchik Records 21–  
16 22. And he will also testify that the use of the thermal wire loop in a LEEP procedure  
17 could very easily cause damage to the bladder wall with the potential for an immediate  
18 or delayed creation of a vesicovaginal fistula. The fact that this procedure was done  
19 and no bladder injury occurred supports that the mesh was located in a plane that was  
20 too superficial, thereby further away from the bladder, which escaped injury from the  
21 thermal electrode of the LEEP procedure.

22 Moreover, Dr. Davies will testify the performance of the perineorrhaphy places  
23 Mrs. Sanchez at a higher risk of complication for dyspareunia (pain during sexual  
24 intercourse). Dr. Davies will explain that while areas of mesh erosion can lead to  
25 dyspareunia, Ms. Sanchez has also had two procedures done relatively close together  
26 in time that can themselves lead to dyspareunia. She has had either a perineorrhaphy  
27 and/or levator myorrhaphy done on two occasions during this time frame. The first  
28

was done at the original repair and the second was done at her second mesh excision procedure in October 2010. Dr. Davies will testify that while some of the operative reports describe the procedure as a perineorrhaphy, the use of the levator muscles being brought across the midline suggests that it was a levator myorrhaphy. And he will explain that doing one of these procedures will place a patient at increased risk of dyspareunia. This is particularly true for the second procedure in which she was already complaining of dyspareunia.

Dr. Davies will testify regarding the relevance of Ms. Sanchez's husband's reports of difficulty with full penetration secondary to pain. He will explain that if the mesh erosion and healing has led to scarring and shortening or narrowing of the vaginal canal, it can lead to these very symptoms. Dr. Davies will confirm that such scarring and shortening has never been described in Mrs. Sanchez's records nor in the exam provided by the plaintiff's expert, Dr. Margolis. As a result, he will testify that the more likely cause for Ms. Sanchez's partner's inability to fully penetrate is the performance of not one, but two, perineorrhaphies or levator myorrhaphies, as these procedures narrow the vaginal caliber or lumen, thereby making it seem like the vagina is short, and a partner cannot fully penetrate without pain to the woman.

In addition, in the procedure describing the intraoperative excision and closure of the mesh erosion, Dr. Davies will confirm that the records describe the cutting away the excess vaginal mucosa. He will testify that given that some vaginal mucosa was missing from the vaginal wall at that location, it is unlikely that there would be any excess vaginal mucosa at all. Instead, he will testify that trimming away the vaginal mucosa likely inhibited Mrs. Sanchez' healing process.

# **1. Exhibits To Be Used With The Witness:**

	Title	Author	Date	Ex. Number
1.	Dr. Kerri Wiltchik	[n/a]	07/11/13	[n/a—Will not be offered

1		Deposition			into evidence; will be used
2					only for impeachment
3					purposes]
4	2.	Marian Regional	Healthcare	Various	Joint Ex. 15
5		Medical Records	Professionals		
6		[Bates Range 125-			
7		127]			
8	3.	Dr. Wiltchik	Healthcare	Various	Joint Ex. 15
9		Medical Records	Professionals		
10					
11	4.	Pinnacle Pelvic	Boston	12/12/07	Def. Ex. 121
12		Floor Repair Kits	Scientific		
13		Anterior/Apical	Corp.		
14		Directions for Use			

### III. THIRD AFFIRMATIVE DEFENSE: APPORTIONMENT OF RESPONSIBILITY

Based on plaintiffs' key evidence set forth in the Pre-Trial Conference Order and in plaintiffs' deposition designations, it appears plaintiffs intend to assert and offer evidence in support of their causes of action that Boston Scientific had a feasible alternative design and/or knew of a safer alternative and that Boston Scientific "had actual or constructive knowledge that the larger the size of a permanent mesh implant, the more likely the potential would be for post-implant erosion," and that Dr. Roger Goldberg had "actual or constructive knowledge...that the mesh configuration for the Pinnacle PFR Kit was too large and would likely cause erosions and extrusions." (Final Pre-Trial Conference Order (Dkt. No. 194) at 15:8–15, 17:24–18:4, 24:10–17.)

1 If plaintiffs pursue these arguments and offer such evidence, then they are  
2 opening the door to the contention that Dr. Wiltchik was negligent in her selection of  
3 the Pinnacle. Boston Scientific's Uphold was on the market at the time Dr. Wiltchik  
4 selected the Pinnacle for treatment of Mrs. Sanchez's pelvic organ prolapse. While  
5 Boston Scientific disputes that the Uphold is a safer alternative design for the  
6 Pinnacle, and opposes the introduction of evidence regarding other products not at  
7 issue in this action, including the Uphold, if the Court allows plaintiffs to argue that  
8 the Uphold was a safer alternative design and it was negligent to implant the Pinnacle  
9 when the Uphold was available, the jury should be allowed to apportion fault to Dr.  
10 Wiltchik, who had sole discretion to choose the product for implantation in Ms.  
11 Sanchez.

12 In addition, there are issues with Dr. Wiltchik's treatment of Mrs. Sanchez that  
13 enable a jury to apportion liability, if any, between Boston Scientific and Dr. Wiltchik.  
14 First, there is an indication that the Pinnacle mesh was located in the wrong surgical  
15 plane, including that hydrodissection was not properly done. *See* Marian Records  
16 125-127 (describing placement of the mesh by "tunneling" under the mucosa); Dr.  
17 Kerri Wiltchik Medical Records ("Wiltchik Records") at 21-22 (describing treatment  
18 of erosion by LEEP procedure). Second, Ms. Sanchez has undergone not one, but  
19 two, perineorrhaphies or levator myorrhaphies. A levator myorrhaphy is a type of  
20 posterior repair involving plication of the levator ani muscles. In this type of repair, it  
21 is not the connective tissue on top of the rectum that is plicated from side-to-side, but  
22 rather, the muscular tissue of the side wall that a surgeon stitches on either side to  
23 meet in the midline. *See* Marian Records at 125-127. These operative choices and  
24 techniques of Dr. Wiltchik may be a substantial factor in causing plaintiffs' alleged  
25 dyspareunia and/or the mesh erosion alleged by Ms. Sanchez.<sup>2</sup>

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26 <sup>2</sup> Even if the Court concludes that Dr. Wiltchik was not negligent and fault should not  
27 be apportioned, Boston Scientific is separately entitled to introduce evidence and  
28 argue that various other circumstances and factors, including techniques utilized and

1           **A. Elements Required to Establish Defendant's Third Affirmative**  
2           **Defense: Apportionment of Responsibility.**

- 3           1. That Dr. Wiltchik was negligent; and  
4           2. That the negligence of Dr. Wiltchik was a substantial factor in  
5           Rosanne Sanchez's harm.

6       *See* CACI 406.

7           The following witnesses will offer testimony in support of this affirmative  
8       defense:

9           **B. Offer of Proof for Witness Dr. Carol Karamitsos:**

10          Dr. Karamitsos assisted Dr. Wiltchik for Ms. Sanchez's surgical procedure.  
11       Karamitsos Dep. at 32:17–19. Dr. Karamitsos will provide testimony regarding the  
12       procedures performed on Ms. Sanchez. *Id.* at 46:20–47:1, 50:21–52:9, 52:18–22,  
13       53:2–9, 53:16–54:12, 58:20–59:25.

14          Dr. Karamitsos will also testify that she has criticism of Dr. Wiltchik because of  
15       the differing techniques she used. Karamitsos Dep. at 85:13-16, 86:19-87:5. Dr.  
16       Karamitsos will testify that Dr. Wilchik did not perform a hydrodissection during the  
17       implant procedure. Karamitsos Dep. at 54:21–24. Dr. Wilchik instead used a  
18       sharpened blunt dissection. *Id.* at 55:23–54:3. It is Dr. Karamitsos' custom and  
19       practice to perform a hydrodissection. *Id.* at 55:5-9. A hydrodissection generally  
20       injects saline into the plane of tissue that the implanter intends to place the mesh. *Id.*  
21       at 55:21–22.

22          Dr. Karamitsos will testify that she employs more hydrodissection than Dr.  
23       Wiltchik performed on Ms. Sanchez during the implant procedure. Karamitsos Dep.  
24       at 87:20–88:10. Dr. Karamitsos will testify that she would typically infiltrate up to 60  
25       cc's of injectable saline into the anterior and posterior spaces, which is more fluid than  
26

27       other procedures selected by the treating physicians, caused or contributed to Ms.  
28       Sanchez's claimed injuries.

1 Dr. Wiltchik used in Ms. Sanchez's procedure. *Id.* at 88:12–89:6. The medical  
2 records will show that Dr. Wiltchik only used 10 cc's of lidocaine, which Dr.  
3 Karamitsos will testify is not sufficient. *Id.* at 105:4–106:18, 107:13–21. As she will  
4 describe, Dr. Karamitsos' method opens up the space, allowing her to see if it  
5 blanches; thereby visualizing whether the opening was too superficial. Using  
6 hydrodissection, if she could see more of a rise overall, it would be indicative of a  
7 space that is deeper and more appropriate for mesh placement. *Id.* at 88:14–20. Dr.  
8 Karamitsos will testify that using less volume for hydrodissection could lead to  
9 superficial placement of the device (*Id.* at 108:10–15), and that if she witnessed Dr.  
10 Wiltchik not performing a hydrodissection for Ms. Sanchez's procedure today, she  
11 would tell her that she thinks Dr. Wiltchik should use hydrodissection to dissect. *Id.*  
12 at 97:20–23.

13 Further, Dr. Karamitsos will testify that she does not tack the mesh down in the  
14 midline, she would secure it laterally and try to avoid more of a medial placement of  
15 the suture material. *Id.* at 89:10–13. Dr. Karamitsos would also do the sling and then  
16 finish with the perineorrhaphy, while Dr. Wiltchik performed the perineorrhaphy and  
17 then did the sling. *Id.* at 90:4–6. Dr. Karamitsos will testify that the method she  
18 employs provides for better exposure with a vaginal hiatus that was more capacious  
19 than narrowed down already. *Id.* at 90:6–9; *see also id.* at 91:3–10.

20 Dr. Karamitsos will also testify that she uses different techniques when dealing  
21 with mesh extrusion. Karamitsos Dep. at 85:13–16, 93:2–95:2. Dr. Karamitsos has  
22 no idea whether other surgeons use Dr. Wiltchik's technique. *Id.* at 83:17–19. Dr.  
23 Karamitsos will testify that when she treats mesh extrusion, she tries to hydrodissect  
24 around the area, just very minimally, to try to separate the plane. *Id.* at 93:10–94:2.  
25 This allows less tension on the extrusion so that she can excise the mesh that is  
26 exposed, and then she does not resect any of that mucosa. *Id.* at 94:3–9. She will  
27 testify that the procedure she uses helps to avoid tension on the tissue, and that

avoiding tension is really important to help allow the area to heal appropriately, which once it is healed, there is no more mesh extrusion. *Id.* at 94:10–24. Dr. Karamitsos also does not recall ever performing a perineorrhaphy in connection with excision of mesh. *Id.* at 94:25–95:2. Dr. Karamitsos will testify that she also does not recall ever using silver nitrate in procedures to address mesh extrusion. *Id.* at 74:15–24.

**1. Exhibits To Be Used With The Witness:**

	<b>Title</b>	<b>Author</b>	<b>Date</b>	<b>Ex. Number</b>
1.	Dr. Kerri Wiltchik Deposition	[n/a]	07/11/13	[n/a—Will not be offered into evidence; will be used only for impeachment purposes]
2.	Marian Regional Medical Records [Bates Range 125-127]	Healthcare Professionals	Various	Joint Ex. 15
3.	Dr. Wiltchik Medical Records	Healthcare Professionals	Various	Joint Ex. 15
4.	Pinnacle Pelvic Floor Repair Kits Anterior/Apical Directions for Use	Boston Scientific Corp.	12/12/07	Def. Ex. 121

**C. Offer of Proof for Witness Dr. Matthew Davies:**

With regard to this affirmative defense, Dr. Davies will testify regarding the nature and manner of the procedures performed and associated details from Ms. Sanchez’s implantation surgery in January 2010. More specifically, he will testify

1 that, according to the operative note, Mrs. Sanchez underwent the vaginal  
2 hysterectomy, and the peritoneum, but not the cuff, was closed. He will testify that  
3 Dr. Wiltchik then moved on to the cystocele repair using some hydrodissection with  
4 10 cc of lidocaine, and a vertical incision was made with the scalpel. A blunt  
5 dissection was used to tunnel out to the sacrospinous ligaments and the ischial spines.  
6 Sutures were placed on both sides to help anchor the mesh in its position. He will  
7 testify based on the operative note that the mesh arms were placed into the  
8 sacrospinous ligaments, and that while the note describes the lateral arms being  
9 placed, it does not specifically mention them going in to the arcus tendineus. He will  
10 testify that proximal sutures were threaded through to keep the mesh in place  
11 proximally and that excess mesh was trimmed and was tacked down with a single  
12 stitch in the midline distally near the urethra.

13 Dr. Davies will testify that with both of these incisions then open (the vaginal  
14 cuff and the anterior repair incision), the rectocele was then addressed. He will testify  
15 that the perineorrhaphy was dissected out and then a tunnel was made under the vaginal  
16 mucosa going up to the posterior aspect of the vaginal cuff. He will further testify that  
17 a piece of mesh previously trimmed for the original anterior apical was then placed  
18 over the rectocele all the way up to the vaginal cuff. The sides were anchored in place  
19 with a single stitch of 2-0 vicryl and all the defects began to be closed. He will testify  
20 based on the medical records that the anterior vaginal mucosa was re-approximated  
21 with a single stitch of 0-vicryl and figure of eight sutures for hemostasis. Then the  
22 levator ani muscles were brought together in the midline, similar to a levator  
23 myorrhaphy. The posterior vaginal mucosa was trimmed and re-approximated with 0-  
24 vicryl in a running, locking stitch. Marian Records at 125–127.

25 Further, Dr. Davies will testify about how Dr. Wiltchik's technique increased  
26 the risk of erosion and poor healing because the mesh was located in the wrong  
27 surgical plane. He will explain how that if mesh is located in a superficial plane, the  
28

1 patient is at higher risk for erosion, and that Mrs. Sanchez' surgical mesh was located  
2 in the wrong surgical plane. Dr. Davies will confirm through the medical records that  
3 Mrs. Sanchez had a LEEP procedure done on April 25, 2011. Wiltchik Records 21–  
4 22. And he will also testify that the use of the thermal wire loop in a LEEP procedure  
5 could very easily cause damage to the bladder wall with the potential for an immediate  
6 or delayed creation of a vesicovaginal fistula. The fact that this procedure was done  
7 and no bladder injury occurred supports that the mesh was located in a plane that was  
8 too superficial, thereby further away from the bladder, which escaped injury from the  
9 thermal electrode of the LEEP procedure.

10 Moreover, Dr. Davies will testify the performance of the perineorrhaphy places  
11 Mrs. Sanchez at a higher risk of complication for dyspareunia (pain during sexual  
12 intercourse). Dr. Davies will explain that while areas of mesh erosion can lead to  
13 dyspareunia, Ms. Sanchez has also had two procedures done relatively close together  
14 in time that can themselves lead to dyspareunia. She has had either a perineorrhaphy  
15 and/or levator myorrhaphy done on two occasions during this time frame. The first  
16 was done at the original repair and the second was done at her second mesh excision  
17 procedure in October 2010. Dr. Davies will testify that while some of the operative  
18 reports describe the procedure as a perineorrhaphy, the use of the levator muscles  
19 being brought across the midline suggests that it was a levator myorrhaphy. And he  
20 will explain that doing one of these procedures will place a patient at increased risk of  
21 dyspareunia. This is particularly true for the second procedure in which she was  
22 already complaining of dyspareunia.

23 Dr. Davies will testify regarding the relevance of Ms. Sanchez's husband's  
24 reports of difficulty with full penetration secondary to pain. He will explain that if the  
25 mesh erosion and healing has led to scarring and shortening or narrowing of the  
26 vaginal canal, it can lead to these very symptoms. Dr. Davies will confirm that such  
27 scarring and shortening has never been described in Mrs. Sanchez's records nor in the  
28

exam provided by the plaintiff's expert, Dr. Margolis. As a result, he will testify that the more likely cause for Ms. Sanchez's partner's inability to fully penetrate is the performance of not one, but two, perineorrhaphies or levator myorrhaphies, as these procedures narrow the vaginal caliber or lumen, thereby making it seem like the vagina is short, and a partner cannot fully penetrate without pain to the woman.

In addition, in the procedure describing the intraoperative excision and closure of the mesh erosion, Dr. Davies will confirm that the records describe the cutting away the excess vaginal mucosa. He will testify that given that some vaginal mucosa was missing from the vaginal wall at that location, it is unlikely that there would be any excess vaginal mucosa at all. Instead, he will testify that trimming away the vaginal mucosa likely inhibited Mrs. Sanchez' healing process.

**1. Exhibits To Be Used With The Witness:**

	<b>Title</b>	<b>Author</b>	<b>Date</b>	<b>Ex. Number</b>
1.	Dr. Kerri Wiltchik Deposition	[n/a]	07/11/13	[n/a—Will not be offered into evidence; will be used only for impeachment purposes]
2.	Marian Regional Medical Records [Bates Range 125- 127]	Healthcare Professionals	Various	Joint Ex. 15
3.	Dr. Wiltchik Medical Records	Healthcare Professionals	Various	Joint Ex. 15
4.	Pinnacle Pelvic Floor Repair Kits Anterior/Apical	Boston Scientific Corp.	12/12/07	Def. Ex. 121

1	Directions for Use			
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2 Boston Scientific intends to pursue the affirmative defenses listed above. In the  
3 MDL proceeding, Boston Scientific's affirmative defenses for express and implied  
4 preemption under the federal Food, Drug and Cosmetic Act (Affirmative Defense  
5 Nos. 11, 12, and 13) were dismissed; however, Boston Scientific reserves the right to  
6 pursue these defenses on appeal. Likewise, the MDL court ruled to exclude FDA  
7 evidence from trial in response to Plaintiffs' Motion in Limine No. 1. This ruling  
8 precluded Boston Scientific from pursuing a regulatory compliance defense as pleaded  
9 in its Master Answer (Affirmative Defense Nos. 12 and 14); therefore, Boston  
10 Scientific reserves the right to pursue those defenses on appeal as well. Boston  
11 Scientific also intends to argue that the learned intermediary doctrine applies, and that  
12 the plaintiffs do not have evidence to support their claims of failure to warn. This,  
13 however, is not an affirmative defense; therefore, it is included within the elements  
14 plaintiffs must prove in their claims.

15 Dated: April 15, 2015

Respectfully submitted,

SHOOK HARDY & BACON L.L.P.

By: /s/ Robert T. Adams

Robert T. Adams

Attorneys for Defendant

Boston Scientific Corporation

**PROOF OF SERVICE**

I am employed in the County of Orange, State of California. I am over the age of 18 and not a party to the within action. My business address is 5 Park Plaza, Suite 1600, Irvine, California 92614.

On April 15, 2015, I served on the interested parties in said action the within:

**DECLARATION OF LEAD TRIAL COUNSEL RE: COMPLIANCE WITH  
LOCAL RULES GOVERNING ELECTRONIC FILING**

by placing a true copy thereof in a sealed envelope(s) addressed as stated on the attached mailing list.

☒ (MAIL) I am readily familiar with this firm's practice of collection and processing correspondence for mailing. Under that practice it would be deposited with the U.S. postal service on that same day in the ordinary course of business. I am aware that on motion of party served, service is presumed invalid if postal cancellation date or postage meter date is more than 1 day after date of deposit for mailing in affidavit.

☐ (FAX) I caused such document(s) to be served via facsimile on the interested parties at their facsimile numbers listed above. The facsimile numbers used complied with California Rules of Court, Rule 2003, and no error was reported by the machine. Pursuant to California Rules of Court, Rule 2006(d), I caused the machine to print a report of the transmission, a copy of which is attached to the original of this declaration.

☐ (BY FEDERAL EXPRESS, AN OVERNIGHT DELIVERY SERVICE) By placing a true and correct copy of the above document(s) in a sealed envelope addressed as indicated above and causing such envelope(s) to be delivered to the FEDERAL EXPRESS Service Center, on \_\_\_\_\_, to be delivered by their next business day delivery service on \_\_\_\_\_, to the addressee designated.

☒ (ELECTRONIC FILING) I provided the document(s) listed above electronically through the CM/ECF system pursuant to the instructions set forth in the Local Rules for the United States District Court for the Central District of California.

I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct.

Executed on April 15, 2015, at Irvine, California.

\_\_\_\_\_  
Eva M. Weiler  
(Type or print name)

\_\_\_\_\_  
/s/ Eva M. Weiler  
(Signature)

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